73 have been amended, and claims 11-16, 19-23, 36-40, 43-47, 59, 60, 66-70 and 74-93 have been canceled by this amendment. Upon entry of this amendment, claims 1-10, 17, 18, 24-35, 41, 42, 48-58, 61-65 and 71-73 will be in the present application.

In the Office Action, the Examiner has noted that copies of certain non-US patent references were not provided with Information Disclosure Statements mailed on 13 April 2001 and 29 January 2002, as required by 37 CFR 1.98(a)(2). Copies of those references are respectfully submitted with this response.

In the Office Action, the Examiner has objected to the drawings under 37 CFR 1.83(a) as failing to show every feature of the invention specified in the claims. In response thereto, applicants file, concurrently herewith, a Drawing Amendment in which applicants request that Fig. 3 be amended. Applicants respectfully submit that no new matter is added by the proposed amendment to Fig. 3.

In the Office Action, the Examiner has objected to the Specification as containing certain informalities. Applicants respectfully submit that the amendments to the Specification set forth herein address all of the Examiner's objections.

The Examiner has also objected to the claims as containing certain informalities. The amendments to the claims set forth herein addresses the Examiner's objections.

The Examiner has rejected claims 1-10, 17-18, 24-26, 27-35, 39, 41-41, 48-50, 51-58, 61-65 and 71-73 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicant respectfully submits that the amendments to the claims made herein

obviate the Examiner's rejection of the claims under 35 U.S.C. §112, second paragraph. Applicant thus requests withdrawal of that rejection.

The Examiner has also rejected claims 1-5, 17-18, 24-26, 51-53, 55, 64-65 and 71-73 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,099,504 to Gross et al. Applicants respectfully traverse that rejection. Gross et al. is directed to a gas-powered self-injection device that includes a sleeve 20 that is movable from the position depicted in Fig 1. to the position depicted in Fig. 4, for example. In addition to being axially movable as just described, the sleeve 20 is rotatable with regard to the barrel 11. See, e.g., column 6, lines 36-47. The movable sleeve 20 functions to prevent the needle from being exposed to the patient. See, e.g., column 7, lines 48-52. Gross et al. does not disclose a limiter portion that is non-movable with respect to a hub portion and a needle cannula such that the needle cannula forward tip extends beyond the skin engaging surface of the limiter portion a distance approximately 0.5 mm to 3.0 mm and wherein the limiter portion limits penetration of the needle into the dermis layer of skin of the animal so that the substance is injected into the dermis layer of the animal, as recited by applicants' claims, as amended herein. See, e.g., amended claims 1 and 51. Applicants respectfully submit that such a feature is neither taught nor suggested by Gross, et al. In fact, the movable sleeve 20 of Gross et al. teaches away from applicants' invention. Thus, applicants respectfully submit that Gross at al. is not a proper 35 U.S.C. §102(e) reference as it fails to teach each limitation recited by claims 1-5, 17-18, 24-26, 51-53, 55, 64-65 and 71-73, as required of a 35 U.S.C. §102(e) reference. For the reasons set forth above, applicant respectfully submits that Gross et al. fails to teach or suggest all the limitations recited by claims 1-5, 17-18, 24-26, 51-53, 55, 64-65 and 71-73, and applicants respectfully submit that those claims are not anticipated by that reference.

Applicants respectfully submit that the Examiner's rejection of claims 1-5, 17-18, 24-26, 51-53, 55, 64-65 and 71-73 as anticipated by Gross et al. is no longer tenable, and respectfully request withdrawal of that rejection.

Applicants further respectfully submit that the invention recited by claims 1-5, 17-18, 24-26, 51-53, 55, 64-65 and 71-73 are not rendered obvious by any hypothetical combination of Gross et al. and any other prior art reference in the present application, or with the knowledge of a person of ordinary skill in the art. Thus, applicants submit that claims 1-5, 17-18, 24-26, 51-53, 55, 64-65 and 71-73 are patentable over the prior art of record, and respectfully request allowance of those claims.

The Examiner has also rejected claims 26 and 73 under 35 U.S.C. §102(e) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as unpatentable over Gross et al. Applicants traverse that rejection. With regard to the Examiner's rejection of claims 26 and 73 under 35 U.S.C. §102(e), the shortcomings of the disclosure of Gross et al. set forth in detail above are not overcome with regard to claims 26 and 73. Thus, those claims are not anticipated by Gross et al. for the same reasons set forth above. With regard to the Examiner's rejection of claims 26 and 73 under 35 U.S.C. §103(a), applicants respectfully submit that, in view of the express teaching of Gross et al. to provide a movable sleeve, the knowledge of a person of ordinary skill in the art would not overcome the deficiency in the teaching of Gross et al., as set forth above. Thus, claims 26 and 73, which respectively depend from claims 1 and 51, are neither anticipated nor rendered obvious by Gross et al. ("If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988; MPEP §2143.03).

The Examiner has also rejected claims 6-9, 27-34, 39, 41-42, 48-50, 54-57 and 61-63 under 35 U.S.C. §103(a) as unpatentable over Gross et al. in view of U.S. Patent No. 5,873,856 (or 5,417,662) to Hjertman et al., and further in view of U.S. Patent No. 5,147,328 to Dragosits, et al. Applicants respectfully traverse that rejection. The teaching of Hjertman et al. and/or Dragosits et al., whether considered alone or in combination with each other and/or with Gross et al., do not overcome the deficiency in the teaching of Gross et al., as set forth in detail above. Thus, the Examiner's proposed combination of those references do not render applicants' invention obvious. Based upon the disclosure of Gross et al. regarding the desirability of hiding the needle both before and after injection, there is simply no motivation to make the sleeve of Gross et al. non-movable, as is the case with applicants' invention.

Consequently, applicants respectfully submit that their invention, as recited by claims 1-10, 17, 18, 24-35, 41, 42, 48-58, 61-65 and 71-73, is patentable over the prior art of record, and respectfully request allowance of all claims pending in the present application.

In view of the foregoing amendments and remarks, applicants respectfully submit that this amendment is fully responsive to the Office Action, and that claims 1-10, 17, 18, 24-35, 41, 42, 48-58, 61-65 and 71-73 are patentable over the prior art of record in the present application, and are thus in condition for allowance.

In the Office Action, the Examiner has also provisionally rejected claims 1, 27 and 51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 32 of copending Application No. 09/417, 671, now U.S. Patent No. 6,494,865. Filed concurrently herewith is a Terminal Disclaimer in compliance with 37 CFR 1.321(c). Also filed concurrently herewith is a Statement Under 37 CFR 3.73(b).

Attached hereto is a marked-up version of the changes made to the specification and claims by this amendment. The attached pages are titled **"VERSION WITH MARKINGS TO SHOW CHANGES MADE TO THE SPECIFICATION AND CLAIMS."**

Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Amendment, including the fees required for applicants' requested extension of time, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

Dated: January 27, 2002

By: David M. Fortunato

David M. Fortunato
Attorney for Applicant(s)
Reg. No. 42,548
(201) 847-6940

VERSION TO SHOW CHANGES MADE TO THE SPECIFICATION AND CLAIMS

IN THE SPECIFICATION

[0011] Also, in the preferred embodiment of the assembly, the limiter portion and the hub portion are integrally formed as a single component, with the needle cannula fixedly attached to the hub portion of the single component behind the skin engaging surface of the limiter portion, with the hub portion including a throat for receiving the prefillable container and with the needle cannula fixedly attached to the hub portion with an adhesive. In addition, the skin engaging surface comprises a rigid polymer having an elastomeric central area with the needle cannula extending therethrough. Further, the substance includes an influenza vaccine. Still further, the needle assembly is attachable to a prefillable container with a ~~Leur~~ Luer fit.

[0016] In addition, in the preferred embodiment, the skin engaging surface comprises a rigid polymer having an elastomeric central area with the needle cannula extending therethrough, and needle assembly is attachable to a prefillable container with a ~~Leur~~ Luer fit. Also, a sleeve circumscribes the limiter and is slidable for shielding the forward tip subsequent to administering an intradermal injection, with the limiter including at least one ramp allowing the limiter to be moved toward the forward tip and preventing the limiter from being moved away from the forward tip upon shielding the forward tip. The assembly may also include a tip cap removably affixed to the skin engaging surface and having the forward tip received therein. Further, the limiter may include a needle plunger slidably received thereby and oriented generally perpendicular to the axis of the needle cannula, with the needle plunger preferably depressable thereby bending the needle cannula and retracting the needle cannula into the limiter for shielding the forward tip subsequent to administering an injection. In addition, a forward cap is

matable to a rearward cap wherein the caps enclose the needle assembly therebetween, with the forward cap and the rearward cap forming a sterile enclosure for storing the needle assembly.

[0042] The needle cannula 36 includes a rearward needle end 40 that extends through the sheath 34 into the throat 18 of the hub portion 14. When the prefillable container 20 is inserted into the throat 18 the rearward needle end 40 is in fluid communication with the prefillable container 20 thereby allowing the substance disposed within the prefillable container 20 to be expelled through the needle cannula 36. Preferably, the prefillable container 20 will be inserted into the throat 18 just prior to administering the intradermal injection. The rearward needle end 40 may be extended and pointed (not shown) to be able to pierce the sealed prefillable container making the fluid connection. The throat 18 includes a tapered bottom 21 adapted to retain the inserted prefillable container 20 through a ~~Leur~~ Luer Slip connection as is well known in the art of syringe retention. Alternatively, a ~~Leur~~ Luer Lok connection (not shown) may be utilized to retain the prefillable container 20 within the throat 18.

[0044] The limiter portion 12 surrounds the needle cannula 36 and extends away from the hub portion 14 toward the forward tip 42 of the needle cannula 36. The limiter portion 12 includes an opening or aperture 48 which closely receives the needle cannula 36 and a generally flat skin engaging surface 46 extending in a plane 146 that is generally perpendicular to the axis of the needle cannula 36 within about fifteen degrees of perpendicular or more preferable within about five degrees. The skin engaging surface 46 is adapted to be received against the skin of the animal to administer an intradermal injection of the substance. The skin engaging surface 46 is represented as being generally flat and continuous and provides for a stable placement of the needle assembly 10 against the animal's skin. Referring to Figure 6A, the skin engaging surface

may include an annular groove 47 with a central surface 49 circumscribing the needle cannula. Figure 6B shows a skin engaging surface 46 having a plurality of spokes 51 projecting outwardly from the central surface 49 in a plane generally parallel to that of the central surface 49. The skin engaging surface 46 provides stability for the device during injection and preferably has a cross-section of at least 5 mm or between 5 to 20 mm.

[0052] As will now be understood, the intradermal delivery device 10 of this invention includes a needle enclosure means, which encloses or conceals the needle cannula tip 42 following injection and which preferably cannot be retracted to prevent accidental needle contact or reuse. In one embodiment shown in Figures 7 and 8, the assembly includes an extendable shield 312, which locks in the extended position, preventing contact with the needle cannula 36. In another embodiment shown in Figures 9 and 10, the needle cannula 36 is bent or deformed beyond its elastic limit by needle plunger 412 to permanently enclose the forward tip 42 within the limiter 414. ~~Alternatively, the needle assembly may be retractable as disclosed, for example, in a copending application Serial No. _____, filed _____ entitled "Prefillable Intradermal Injector," the disclosure of which is incorporated by reference.~~

IN THE CLAIMS

1. (Amended) An intradermal needle assembly for use with a prefillable container having a reservoir capable of storing a substance for injection into the skin of an animal comprising:

a hub portion being attachable to the prefillable container storing the substance;

a needle cannula supported by said hub portion and having a forward tip extending away from said hub portion; and

a limiter portion surrounding said needle cannula and extending away from said hub portion toward said forward tip of said needle cannula, said limiter including a generally flat skin engaging surface extending in a plane generally perpendicular to an axis of said needle cannula and adapted to be received against the skin of the animal to administer an intradermal injection of the substance, said ~~needle~~ limiter portion being non-movable with respect to said hub portion and said needle cannula such that said needle cannula forward tip ~~extending~~ extends beyond said skin engaging surface a distance approximately 0.5 mm to 3.0 mm and wherein said limiter portion limits penetration of the needle into the dermis layer of skin of the animal so that the ~~vaccine~~ substance is injected into the dermis layer of the animal.

2. ~~An~~ (Amended) The assembly as set forth in claim 1 wherein said plane is generally perpendicular to said axis of said needle cannula within about fifteen degrees.

3. ~~An~~ (Amended) The assembly as set forth in claim 1 wherein said plane is generally perpendicular to said axis of said needle cannula within about five degrees.

4. ~~An~~ (Amended) The assembly as set forth in claim 1 wherein said hub portion and said limiter portion are formed as separate pieces.

5. ~~An~~ (Amended) The assembly as set forth in claim 4 wherein said limiter portion defines an inner cavity receiving at least a portion of said hub and including an abutment engaging a corresponding structure on said hub portion thereby limiting the length of said needle cannula extending beyond said skin engaging surface.

6. ~~An~~ (Amended) The assembly as set forth in claim 5 wherein said hub portion includes a throat for receiving the prefillable container.

7. ~~An~~ (Amended) The assembly as set forth in claim 6 wherein said needle cannula is fixedly attached to said hub portion.

8. ~~An~~ (Amended) The assembly as set forth in claim 7 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

9. ~~An~~ (Amended) The assembly as set forth in claim 8 wherein said adhesive comprises an epoxy curable with ultra violet light.

10. ~~An~~ (Amended) The assembly as set forth in claim 9 wherein said limiter portion includes a plurality of snaps engaging said hub portion thereby fixedly attaching said hub portion to said limiter portion.

17. ~~An~~ (Amended) The assembly as set forth in claim 1 wherein said substance includes an influenza vaccine.

18. ~~An~~(Amended) The assembly as set forth in claim 1 wherein said needle assembly is attachable to a prefillable container with a ~~Leur~~ Luer fit.

24. ~~An~~(Amended) The assembly as set forth in claim 1 further including a forward cap being matable to a rearward cap wherein said forward and rearward caps enclose said needle assembly therebetween.

25. ~~An~~(Amended) The assembly as set forth in claim 24 wherein said forward cap and said rearward cap form a sterile enclosure for storing said needle assembly.

26. ~~An~~(Amended) The assembly as set forth in claim 1 wherein said skin engaging surface includes an outer diameter of at least 5 mm.

27. (Amended) An intradermal needle assembly for use with a prefillable container having a reservoir capable of storing a substance for injection into the skin of an animal comprising:

a hub portion having a throat for receiving the prefillable container;

a needle cannula being supported by said hub portion and having a forward tip extending away from said hub portion;

a limiter portion surrounding said hub portion and said needle cannula and extending away from said hub portion toward said forward tip of said needle, said limiter portion including a generally flat skin engaging surface extending in a plane generally perpendicular to an axis of said needle cannula and being adapted to be received against the skin of an animal to

receive an intradermal injection of ~~a~~ the ~~vaccine~~ substance, said limiter portion being non-movable with respect to said hub portion and said needle cannula such that said forward tip ~~extending~~ extends beyond the skin engaging surface from approximately 0.5 mm to approximately 3.0 mm and wherein the limiter portion limits penetration of said needle cannula into the dermis layer of the skin of the animal thereby injecting the substance into the dermis layer of the animal.

28. ~~An~~(Amended) The assembly as set forth in claim 27 wherein said plane is generally perpendicular to said axis of said needle cannula within about fifteen degrees.

29. ~~An~~(Amended) The assembly as set forth in claim 27 wherein said plane is generally perpendicular to said axis of said needle cannula within about five degrees.

30. ~~An~~(Amended) The assembly as set forth in claim 27 wherein said hub portion and said limiter portion are formed as separate pieces.

31. ~~An~~(Amended) The assembly as set forth in claim 30 wherein said limiter portion defines an inner cavity receiving at least a portion of said hub and including an abutment engaging a corresponding structure on said hub portion thereby limiting the length of said needle cannula extending beyond said skin engaging surface.

32. ~~An~~(Amended) The assembly as set forth in claim 31 wherein said needle cannula is fixedly attached to said hub portion.

33. ~~An~~(Amended) The assembly as set forth in claim 32 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

34. ~~An~~(Amended) The assembly as set forth in claim 33 wherein said adhesive comprises an epoxy curable with ultra violet light.

35. ~~An~~(Amended) The assembly as set forth in claim 27 wherein said limiter portion includes a plurality of snaps engaging said hub portion thereby fixedly attaching said hub portion to said limiter portion.

41. ~~An~~(Amended) The assembly as set forth in claim 27 wherein said substance includes an influenza vaccine.

42. ~~An~~(Amended) The assembly as set forth in claim 27 wherein said needle assembly is attachable to a prefillable container with a ~~Leur~~ Luer fit.

48. ~~An~~(Amended) The assembly as set forth in claim 27 further including a forward cap being matable to a rearward cap wherein said forward and rearward caps enclose said needle assembly therebetween.

49. ~~An~~(Amended) The assembly as set forth in claim 48 wherein said forward cap and said rearward cap form a sterile enclosure for storing said needle assembly.

50. ~~An~~(Amended) The assembly as set forth in claim 27 wherein said skin engaging surface includes an outer diameter of at least 5 mm.

51. (Amended) An intradermal needle assembly attachable to a prefillable container having a reservoir adapted to contain a substance for use in intradermally injecting ~~vaccines~~ the substance into the skin of an animal, comprising:

a needle cannula affixed to a hub portion and being in fluid communication with the outlet port, ~~the~~ said needle cannula having a forward tip that is adapted to penetrate an the skin of an animal; and

a limiter surrounding said needle cannula and having a generally flat skin engaging surface extending in a plane ranging between five and fifteen degrees from perpendicular to an axis of said needle cannula and being adapted to be placed against the skin of the animal to administer an intradermal injection of the substance, said limiter portion being non-movable with respect to said hub portion and said needle cannula such that said needle cannula forward tip ~~extending~~ extends away from said skin engaging surface from approximately 0.5 mm to approximately 3.0 mm ~~such~~ and ~~that~~ wherein said limiter limits penetration of said forward tip into the dermis layer of the skin of an animal so that the substance is injected into the dermis layer of the skin.

52. ~~An~~(Amended) The assembly as set forth in claim 51 wherein said hub portion and said limiter portion are formed as separate pieces.

53. ~~An~~(Amended) The assembly as set forth in claim 51 wherein said limiter portion defines an inner cavity receiving at least a portion of said hub and including an abutment engaging a corresponding structure on said hub portion thereby limiting the length of said needle cannula extending beyond said skin engaging surface.

54. ~~An~~(Amended) The assembly as set forth in claim 51 wherein said hub portion includes a throat for receiving the prefillable container.

55. ~~An~~(Amended) The assembly as set forth in claim 51 wherein said needle cannula is fixedly attached to said hub portion.

56. ~~An~~(Amended) The assembly as set forth in claim 55 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

57. ~~An~~(Amended) The assembly as set forth in claim 56 wherein said adhesive comprises an epoxy curable with ultra violet light.

58. ~~An~~(Amended) The assembly as set forth in claim 57 wherein said limiter portion includes a plurality of snaps engaging said hub portion thereby fixedly attaching said hub portion to said limiter portion.

61. ~~An~~(Amended) The assembly as set forth in claim 51 wherein said hub portion includes a throat for receiving the prefillable container.

62. ~~An~~(Amended) The assembly as set forth in claim 61 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

63. ~~An~~(Amended) The assembly as set forth in claim 62 wherein said adhesive comprises an epoxy curable with ultra violet light.

64. ~~An~~(Amended) The assembly as set forth in claim 51 wherein said substance includes an influenza vaccine.

65. ~~An~~(Amended) The assembly as set forth in claim 51 wherein said needle assembly is attachable to a prefillable container with a ~~Leur~~ Luer fit.

71. ~~An~~(Amended) The assembly as set forth in claim 51 further including a forward cap being matable to a rearward cap wherein said forward and rearward caps enclose said needle assembly therebetween.

72. ~~An~~(Amended) The assembly as set forth in claim 71 wherein said forward cap and said rearward cap form a sterile enclosure for storing said needle assembly.

73. ~~An~~(Amended) The assembly as set forth in claim 51 wherein said skin engaging surface includes an outer diameter of at least 5 mm.